IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., PLAINTIFF, -V.- FRESENIUS KABI USA, LLC., DEFENDANT.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Merck Sharp & Dohme Corp. ("Merck"), by and through its undersigned attorneys, for its Complaint against Defendant Fresenius Kabi USA, LLC ("Fresenius") alleges, upon knowledge with respect to Defendant's acts and upon information and belief as to other matters, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 9,023,790 (the "'790 Patent") and 9,358,297 (the "'297 Patent") arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 209983, (the "Fresenius ANDA"), which Fresenius filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of a generic version of Merck's NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL), which is sold in the United States. The Fresenius

posaconazole product described in the Fresenius ANDA is referred to herein as the "ANDA Posaconazole Product."

THE PARTIES

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

3. Defendant Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at Three Corporate Drive, Lake Zurich, IL 60047. Fresenius develops, formulates, manufactures, markets and sells pharmaceutical drug products in the United States.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

5. This Court has personal jurisdiction over Fresenius at least because Fresenius is a Delaware limited liability company.

6. This Court also has personal jurisdiction over Fresenius by virtue of its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of Delaware through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from

the sales and marketing of generic drug products within this judicial district, and through its intent to market and sell the ANDA Posaconazole Product, if approved, in this judicial district and to residents of this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

NOXAFIL®

8. Merck is the holder of New Drug Application ("NDA") N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the registered trademark NOXAFIL® ("NOXAFIL® for Injection"). NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

9. NOXAFIL® for Injection is an embodiment of one or more claims of the '790 Patent and the '297 Patent (collectively, the "Patents-in-Suit"). The Patents-in-Suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®.

PATENTS-IN-SUIT

10. The '790 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted □-Cyclodextrin," was duly and legally issued by the USPTO on May 5, 2015. The '790 Patent is set to expire on July 4, 2031. Merck is the owner of all title, right and interest in and to the '790 Patent by assignment. A copy of the '790 Patent is attached as Exhibit A.

11. The '297 Patent, entitled "Posaconazole Intravenous Solution Formulations Stabilized by Substituted □-Cyclodextrin" was duly and legally issued by the USPTO on June 7, 2016. The '297 Patent is set to expire on June 24, 2031. Merck is

the owner of all title, right and interest in and to the '297 Patent by assignment. A copy of the '297 Patent is attached as Exhibit B.

FRESENIUS'S ANDA

12. Fresenius filed or caused to be filed the Fresenius ANDA with the FDA, seeking FDA approval to market and sell within the United States the ANDA Posaconazole Product before the expiration of the Patents-in-Suit.

13. The Fresenius ANDA identified Merck's NOXAFIL® for Injection product and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents-in-Suit are invalid or otherwise will not be infringed by the ANDA Posaconazole Product.

14. On or after December 22, 2017, Merck received a letter from Fresenius, dated December 21, 2017, stating that pursuant to § 505(j)(2)(B)(i) and (ii), Fresenius had submitted the Fresenius ANDA to the FDA. The letter to Merck stated that the Patents-in-Suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the ANDA Posaconazole Product.

15. By filing or causing to be filed the Fresenius ANDA, Fresenius necessarily represented to the FDA that the ANDA Posaconazole Product has the same active ingredient as NOXAFIL® for Injection, has the same method of administration, dosage form, and strength as NOXAFIL® for Injection and is bioequivalent to NOXAFIL® for Injection.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,023,790

16. Merck incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17. By filing or causing to be filed the Fresenius ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the ANDA Posaconazole Product before the expiration of the '790 Patent, Fresenius committed an act of infringement under 35 U.S.C. § 271(e)(2).

18. If Fresenius commercially makes, uses, offers to sell or sells the ANDA Posaconazole Product within the United States, or imports the ANDA Posaconazole Product into the United States, or induces or contributes to any such conduct during the term of the '790 Patent, Fresenius would further infringe the '790 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

19. Fresenius's commercial manufacture, use, offer to sell, or sale of the ANDA Posaconazole Product within the United States, or importation of the ANDA Posaconazole Product into the United States, during the term of the '790 Patent, would infringe the '790 Patent.

20. Upon approval of the Fresenius ANDA, and the commercial marketing of the ANDA Posaconazole Product, Fresenius would actively induce and/or contribute to infringement of the '790 Patent. At least in light of the prescribing instructions Fresenius proposes to provide in connection with the ANDA Posaconazole Product, Fresenius will induce health care professionals, resellers, pharmacies, and end users of the ANDA Posaconazole Product to directly infringe one or more claims of the '790 Patent. Fresenius will encourage acts of direct infringement with knowledge of the '790 Patent and knowledge that it is encouraging infringement.

21. Fresenius had actual and constructive knowledge of the '790 Patent prior to filing the Fresenius ANDA, and was aware that the filing of the Fresenius

ANDA with the request for FDA approval before the expiration of the '790 Patent would constitute an act of infringement of the '790 Patent.

22. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,358,297

23. Merck incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

24. By filing or causing to be filed the Fresenius ANDA with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the ANDA Posaconazole Product before the expiration of the '297 Patent, Fresenius committed an act of infringement under 35 U.S.C. § 271(e)(2).

25. If Fresenius commercially makes, uses, offers to sell or sells the ANDA Posaconazole Product within the United States, or imports the ANDA Posaconazole Product into the United States, or induces or contributes to any such conduct during the term of the '297 Patent, Fresenius would further infringe the '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Fresenius's commercial manufacture, use, offer to sell, or sale of the ANDA Posaconazole Product within the United States, or importation of the ANDA Posaconazole Product into the United States, during the term of the '297 Patent, would infringe the '297 Patent.

27. Upon approval of the Fresenius ANDA, and the commercial marketing of the ANDA Posaconazole Product, Fresenius would actively induce and/or contribute to infringement of the '297 Patent. At least in light of the prescribing

instructions Fresenius proposes to provide in connection with the ANDA Posaconazole Product, Fresenius will induce health care professionals, resellers, pharmacies, and end users of the ANDA Posaconazole Product to directly infringe one or more claims of the '297 Patent. Fresenius will encourage acts of direct infringement with knowledge of the '297 Patent and knowledge that it is encouraging infringement.

28. Fresenius had actual and constructive knowledge of the '297 Patent prior to filing the Fresenius ANDA, and was aware that the filing of the Fresenius ANDA with the request for FDA approval before the expiration of the '297 Patent would constitute an act of infringement of the '297 Patent.

29. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment in its favor and against Defendant and respectfully requests the following relief:

A. A judgment that Defendant has infringed one or more claims of the '790 Patent under 35 U.S.C. § 271(e)(2) by submitting the Fresenius ANDA;

B. A judgment that Defendant has infringed one or more claims of the '297 Patent under 35 U.S.C. § 271(e)(2) by submitting the Fresenius ANDA;

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product

that infringes the '790 Patent, including the product described in the Fresenius ANDA, prior to the expiration of the '790 Patent, including any extensions;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '297 Patent, including the product described in the Fresenius ANDA, prior to the expiration of the '297 Patent, including any extensions;

E. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Fresenius ANDA, or inducing or contributing to such conduct, would constitute infringement of the '790 Patent by Defendant pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (f);

F. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Fresenius ANDA, or inducing or contributing to such conduct, would constitute infringement of the '297 Patent by Defendant pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (f);

G. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Fresenius ANDA be a date that is not earlier than the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

H. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Fresenius ANDA be a date that is not earlier than the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

I. If Defendant commercially manufactures, uses, offers to sell, sells or imports the product described in the Fresenius ANDA prior to the expiration of the '790 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

J. If Defendant commercially manufactures, uses, offers to sell, sells or imports the product described in the Fresenius ANDA prior to the expiration of the '297 Patent or any later expiration of exclusivity to which Plaintiff is or becomes entitled, a judgment awarding Plaintiff monetary relief, together with interest;

K. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

L. Such other and further relief as the Court deems just and proper.

February 2, 2018

MCCARTER & ENGLISH, LLP

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